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09/703,518	10/31/2000	Jessica G. Chiu	25141-1800	1874

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EXAMINER	
PHANIJPHAND, GWEN G	
ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/703,518	Applicant(s) CHIU ET AL.	
	Examiner Gwen Phanijphand	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Information Disclosure Statement is missing. Please submit a copy.

Claim Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4, 5, 6, 14, 15, and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 6,315,794 B1 to Richter.

Regarding claim 1, Richter discloses in Fig. 3B a catheter, having a component (a stent) having a radiopaque marker, comprising a first layer of radiopaque material (102) and a second layer of radiopaque material (202) on the first layer, having a thickness greater than a thickness of the first layer (col. 4, ll. 46-49).

Regarding claim 4, Richter discloses the first and second layers of radiopaque material formed of the same radiopaque material (col. 4, ll. 65-67).

Regarding claim 5, Richter discloses in col. 5, ll. 20-25 the first layer of radiopaque material having a smaller particle size than the second layer of radiopaque material (col. 4, ll. 65-67, since the layers can made of different materials)

Regarding claim 6, Richter discloses the first layer of radiopaque material being of different material than the second layer of radiopaque material (col. 4, ll. 65-67).

Regarding claim 14, Richter discloses the thickness of the first layer is about 0.001 mm to about 0.01 mm (col. 5, ll. 20-31).

Regarding claim 15, Richter discloses the thickness of the second layer is about 0.02 mm to about 0.025 mm (col. 5, ll. 20-31).

Regarding claim 16, Richter discloses the second layer has a length of about 0.05 mm to about 1.5 mm (col. 5, ll. 20-31).

2. Claims 1-3, 6-8, 10, 19, 20, 21, 24 and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,858,556 to Eckert et al.

Regarding claim 1, Eckert et al. disclose in Fig. 5 and in col. 4, ll. 1-5 a catheter having a component (a stent) having a radiopaque marker, comprising a first layer of radiopaque material (24) and a second layer of radiopaque material (24) on the first layer. A second layer of the same material can be continually deposited, after a first layer is deposited, until the second layer has a thickness greater than that of the first layer (col. 3, ll. 57-60).

Regarding claim 2, Eckert et al. disclose in Fig. 6 the first layer of radiopaque material comprising a deposited layer of radiopaque material on an outer surface of the catheter component, and the second layer of radiopaque material comprising an electroplated layer of radiopaque material on an outersurface of the first layer of radiopaque material (col. 3, ll.39-47; col. 4, ll. 2-5).

Regarding claim 3, Eckert et al. disclose the second layer of radiopaque material can extend the entire length of the first layer (Fig. 1). In the abstract, Eckert et al. also disclose that the tube is formed and surrounded by radiopaque and biocompatible material.

Regarding claim 6, Eckert et al. disclose the first layer of radiopaque material being different from the second layer of radiopaque material (col. 3; ll.43-45). If the first layer is stainless steel then the second layer, can be tantalum.

Regarding claim 7, Eckert et al. disclose in claim 10 the first layer of radiopaque material comprising a blend of a polymeric and radiopaque material.

Regarding claim 8, Eckert et al. disclose the second layer comprising an electroplated layer of radiopaque material on the blended first layer. As in claim 10, the radiopaque material of one layer can be platinum alloy, and an outer layer (col. 3, ll. 39-45; col. 4,18-20) can be a radiopaque material such as stainless steel.

Regarding claim 10, Eckert et al. disclose the catheter component being a catheter shaft (Abstract).

Regarding claim 19, Eckert et al. disclose a method of making a radiopaque marker for a catheter component and electroplating a second layer of radiopaque material (Fig. 6, 12, 14, 16) onto an outer surface of the first layer of radiopaque material (col. 4, ll. 2-5).

Regarding claim 20, Eckert et al. disclose depositing the first layer by thin film deposition (col. 4, ll.2-5).

Regarding claim 21, Eckert et al. disclose the first layer is deposited by a thin film deposition technique selected from the group consisting of chemical vapor deposition and physical vapor deposition (col. 4, ll.2-5).

Regarding claim 24, Eckert et al. disclose the catheter component being a catheter shaft with a second, thicker layer of radiopaque material electroplated onto the first layer (col.3, ll.57-60; col. 4, ll.2-5). Eckert et al. further disclose that the layer of radiopaque material can vary in thickness, and since the radiopaque material is deposited in layers, a second layer can be deposited more thickly than the first layer.

Regarding claim 26, Eckert et al. disclose electroplating a layer of radiopaque material onto an outersurface of at least a section of a catheter component, comprising a blend of polymeric and radiopaque material (col. 4, ll. 50-54).

3. Claims 1, 7, 11, and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,873,904 to Ragheb et al.

Regarding claim 1, Ragheb et al disclose in col. 3, ll.49-60 an intraluminal catheter component with at least one radiopaque marker, comprising a first layer of radiopaque material and a second layer of radiopaque material on the first layer, having a thickness greater than the thickness of the first layer. A second layer of the same material can be continually deposited, after a first layer is deposited, until the second layer has a thickness greater than that of the first layer.

Regarding claim 7, Ragheb et al disclose the first layer of radiopaque material comprising a blend of a polymeric and radiopaque material (col. 3, ll. 55-60; col. 4, ll.4-5).

Regarding claim 11, Ragheb et al disclose the catheter component is an inflatable balloon (col. 3, ll. 49-51).

Regarding claim 26, Ragheb et al disclose electroplating a layer of radiopaque material onto an outersurface of at least a section of a catheter component, and the section of the catheter component comprising a blend of a polymeric material and a radiopaque material (col. 3, ll.55-60).

4. Claims 1, 11-13, 17 and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,797,868 to Leone.

Regarding claim 1, Leone discloses a catheter having a component, having a radiopaque marker, comprising a first layer of radiopaque material and a second layer of radiopaque material on the first layer, having a thickness greater than a thickness of the first layer (col. 5, ll.12-17). The second layer can be continually deposited until the second layer has a thickness greater than a thickness of the first layer, and both layers can be composed of the same material.

Regarding claim 11, Leone discloses the catheter component is a balloon (col. 5, ll.12-17).

Regarding claim 12, Leone discloses the distal radiopaque marker at a distal and proximal end of the working length of the balloon (Fig. 3, 25b and Fig. 4, 25c). The proximal and distal radiopaque markers each comprise a first layer of radiopaque material, and a second layer of radiopaque material on the first layer, having a thickness greater than the thickness of the first layer. The second layer can be continually deposited until the second layer has a thickness greater than a thickness of the first layer, and both layers can be composed of the same material.

Regarding claim 13, Leone discloses each of the distal and proximal radiopaque markers have a length (Fig. 1, 29) substantially less than a length of a working length of the balloon. The radiopaque marker (Fig. 4, 25c) does not necessarily cover the entire length of the working length of the balloon unless that is the desired effect.

Regarding claim 17, Leone discloses a balloon catheter (col. 5,ll. 12-17) comprising an elongated catheter shaft, a balloon on a distal section of the catheter (Fig. 1), having a working length (29), and at least one radiopaque marker on the surface of the working length of the

balloon. The radiopaque marker does not necessarily cover the entire length of the working length of the balloon unless that is the desired effect (Fig. 4, 25c).

Regarding claim 18, Leone discloses the catheter wherein comprises at least one distal radiopaque marker on the distal end of the working length of the balloon (Fig. 3, 25b) and a proximal radiopaque marker on the proximal end of the working length of the balloon (Fig. 4, 25c). Leone further discloses a first layer of radiopaque material and a second layer of radiopaque material on the first layer having a thickness greater than a thickness of the first layer. A second layer of the same material can be continually deposited, after a first layer is deposited, until the second layer has a thickness greater than that of the first layer.

Claim Rejections – 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 9, 14-16, 22, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,858,556 to Eckert et al.

Regarding claim 9, Eckert et al. disclose a catheter component with radiopaque layers but do not disclose a first section longitudinally spaced from a second section, consisting of a first layer of radiopaque material extending between the sections. It is, however, well known to one having ordinary skill in the art at the time of the invention that methods such as electroplating or

vapor, chemical, or other film techniques to deposit a layer of radiopaque material,can deposit and create the necessary coating length desired for that catheter component. Thus, Eckert et al. did not disclose a specific length for the radiopaque layer, but instead disclosed that the layer can vary (col. 5, ll. 12-20) according to the level of flexibility and luminescence desired since these characteristics help determine which length is best for a procedure. The ability to vary the length of radiopaque coating is advantageous for different procedures and medical devices.

Regarding claims 14, 15, 16, and 25, Eckert et al. disclose first and second electroplated layers but do not disclose the thickness of the first layer being about 0.001 mm to about 0.01 mm and the thickness of the second layer being about 0.02 mm to about 0.025 mm, or more specifically 0.05 mm to being about 1.5 mm. Eckert et al., however, do disclose (col. 3, ll. 57-66) that the layer can vary in thickness. It is well know and obvious to one skilled in the art at the time of the invention to vary thickness of radiopaque materials so that one can adjust the luminescence according to the anatomical area being viewed and according to the radiopaque material(s) being used. The user weighs the natural stiffness of the radiopaque material and the luminescence power, and then determines the desirable thickness of the layers.

Regarding claim 22, Eckert et al. disclose the catheter component but do not disclose depositing the first layer of radiopaque material onto a section of the catheter component having a length substantially less than the length of the catheter component. It is, however, well known to one having ordinary skill in the art at the time of the invention that methods such as electroplating and vapor, chemical, or other film techniques can deposit a layer of radiopaque material at the length desired for that catheter component. Hence, Eckert et al. did not disclose a

specific length for the radiopaque layer, since it is most advantageous to vary (col. 5, ll. 12-20) the length to accommodate the surgical area and tool.

Regarding claim 23, Eckert et al. disclose the catheter component being a stent with a first and second layer, but Eckert et al do not disclose the catheter component being a balloon. It is, however, obvious to one of ordinary skill in the art at the time of the invention that stents and balloons on catheters are very similar devices, are often used together, and are commonly used in the same parts of the body. The method of electroplating a stent with two layers of radiopaque material is well known. Hence, it would obvious to electroplate a balloon with two layers of radiopaque material since, as with stents, the layering of radiopaque materials on the balloon allow the balloon's flexibility and luminescence to be maximized for surgical procedure.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,919,126 to Armini

U.S. Patent No. 5,991,650 to Swanson et al.

U.S. Patent No. 6,210,396 B1 to MacDonald et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP
September 24, 2002

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